





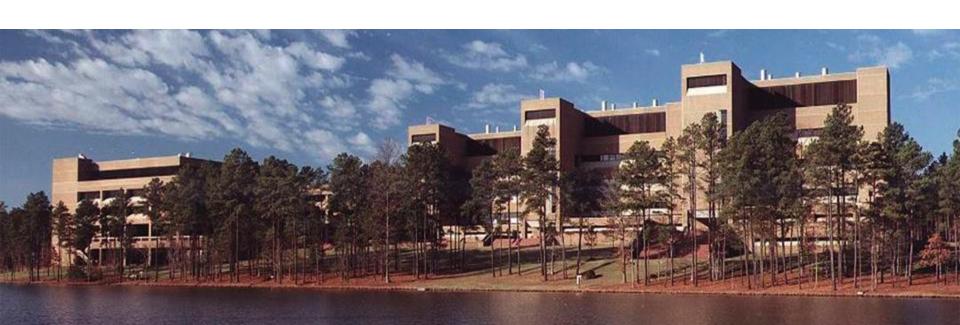
CIHR Best Brains Exchange Ottawa, Canada

Aubrey Miller, MD, MPH February 19, 2016

The National Institute of Environmental Health Sciences

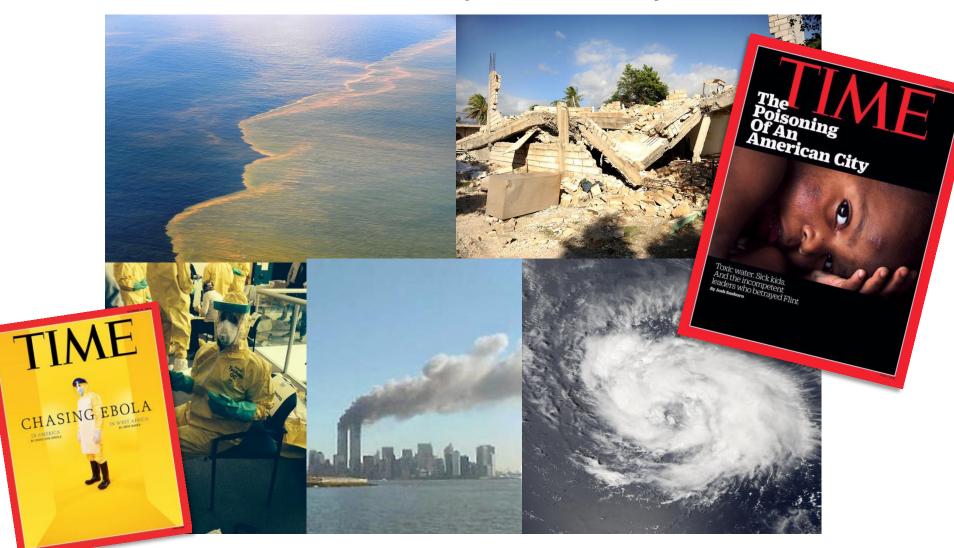
- One of the National Institutes of Health, but located in Research Triangle Park, NC
- Wide variety of programs supporting our mission of environmental health:
 - -- Intramural laboratories
 - Extramural funding programs
 - -- Disease Prevention

- -- Clinical research program
- National Toxicology Program
- -- Public Health Focus



Each disaster presents new issues & uncertainties

Research is vital to inform the response, recovery, and future events



Health Impacts of World Trade Center (WTC) Attack

- Widespread contamination
- USGS identified complex, mixed exposures
- WTC Medical Monitoring program findings
 - Study of 27,500 Responders

Asthma	28 %
ASuma	20

Sinusitis42 %

Lung Tests 42 %

■ PTSD 9 %

Panic 8 %

Depression 28 %





Gulf Oil Spill April 2010 11 workers killed, 17 injured, 98 survivors

Exposures of Concern:

- Oil Components
 - Poly-aromatic hydrocarbons (PAHs)
 - Volatile organic chemicals (VOCs)
 - Heavy metals
- Dispersants
- Burning Particulate

Health Concerns:

- Skin
- Lungs
- Eating contaminated seafood
- Mental health





Gulf Oil Spill April 2010

- Little known about long-term health effects!
- Hundreds of large (>700 tons) tanker oil spills in past 40 years
- Only 8 health studies & all but one was cross-sectional or very short term

Barrels of Oil	$(1 B = \sim 40 \text{ gallons})$
	`

1989 Exxon Valdez, USA	270,000
1993 MV Braer, UK	620,000
1996 Sea Empress, UK	525,000
1997 Nakhodka, Japan	>44,000
1999 Erika, France	146,000
2002 Prestige, Spain	460,000
2003 Tasman Spirit, Pakistan	270,000
2007 Hebei Spirit, South Korea	73,000
2010 Deepwater Horizon, USA	4,900,000



⁻ Dispersant Use > 1.8 M gallons

Gulf Oil Spill: Rapid Public Health Responses

- Acute Symptom Surveillance
 - Sentinel hospitals, Workplace reports, Poison Control Centers

- Focused Surveys of Specific Populations
 - NIOSH worker investigations (Health Hazard Evaluations)
 - Community Assessment for Public Health Emergency Response (CASPER)
 - Community Surveys (e.g., LA Bucket Brigade)

 Acute responses NOT designed to understand longerterm physical and mental health or other consequences

IOM Oil Spill Workshop, New Orleans. June 22-23, 2010



Key Points

- -Longitudinal human health research is clearly indicated
- -Health studies should begin as soon as possible
- -Mental health and psychosocial impacts must not be overlooked
- -Sensitive populations need to be monitored
- -External stakeholders must be part of the process
- -Data and data systems should be developed to support wider research efforts

NIH Gulf Oil Spill: Research Responses







Toxicology Research



Worker Training
Oil Spill Cleanup Initiative

Deepwater Horizon Research Consortia: Health Impacts & Community Resiliency

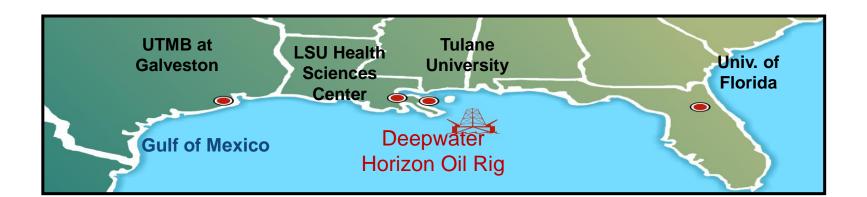
Extramural Research



Deep Water Horizon (DWH) Research Consortium



- Trans-NIH effort of university & community partnerships
- Population-based & lab research
- Studies designed together to assess health impacts on Gulf Coast communities
- Build capacity, train residents, further env. health literacy



Oil Spill Research Challenges

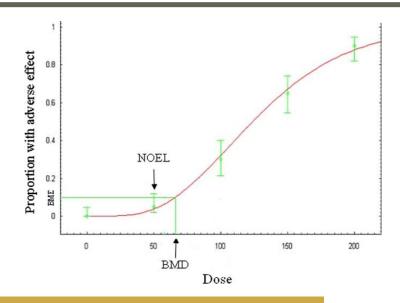
- Study Populations: Workers and Volunteers
 - Use of NIOSH roster & combining multiple lists (BP, national guard)
- Study Development Process
 - IRB, OMB, & Certificates of Confidentiality
- Baseline Data for Comparison
 - Available only for small fraction of cohort (e.g., Coast Guard)
 - Health information, biospecimens, relevant tests ??
- Exposure Reconstruction
 - Multiple databases that need to be integrated
 - Available data difficult to use to reconstruct exposures
- Timeliness of Extramural Awards & Initiation of Studies

Charleston, West Virginia: Elk River Chemical Spill

- Crude 4- methylcyclohexanemethanol (MCHM) plus other chemicals were released from a Freedom Industries facility
- Water use suspended for 300,000 people in nine counties
- >500 hospital visits: reported nausea, vomiting, rashes, lung & eye irritation
- Unknown health effects of released chemical
- Residents told to not drink, bathe, cook or wash with tap water due to uncertainty







Lingering Questions of Concern:

- Can MCHM affect development of an unborn child?
- Are there long-term effects?
- How reliable are the studies on MCHM used to identify a safe level?
- Chance of the spilled chemicals having surprising health effects?

>80,000 chemicals in the US have never been tested for their toxic effects on health & the environment

NTP Studies to Help Assess Various Uncertainties related to MCHM & other chemicals of interest

				S	tudi	es			
Questions of Concern	Rat Prenatal Toxicity	Mouse Dermal Irritation and Hypersensitivity	5-Day Rat Toxicogenomic	DNA Damage Assays	Zebrafish Developmental	Nematode Toxicity	Immune Toxicity Studies	High Throughput Screening	Computer Modeling / Structure Activity Relationship (SAR) Analysis
Can MCHM affect an unborn child?	Х			X	Χ	Χ			X
Are there long-term effects?	Х			X			Χ		X
Reliability of studies for safe level?	Х	X	Χ						
Surprising toxicological effects?				Х	Х	Χ		Х	X

Guideline Non-guideline

Moving from Public Health Practice to Research

- Building on acute response platforms (surveillance, cross sectional)
 - Ad-hoc convenience based investigations to hypothesis driven research
 - Integrating into response activities effectively without impediment
 - Feedback to identify research priorities and opportunities
- Who needs to be looked at?: high-risk groups, kids, elderly, EJ community
- What additional information do we need?: to understand health effects

Missed Opportunities for Key Questions!

- H1N1 Response- treatment research, IRB issues
- DWH Oil Spill 9 months to start GuLF Study
- Hurricane Sandy- 11 months to fund extramural efforts



Need for Environmental & Occupational Health Data

Is it safe?

- For whom, what, when, and where?
- Longer-term physical & mental health impacts?
- Safety of homes, residences, work places

Focal areas of research

- 1. Environmental Exposures
- 2. Health Risks and Effects
- 3. Value of Interventions or Mitigation Strategies
- 4. Ecosystem Effects







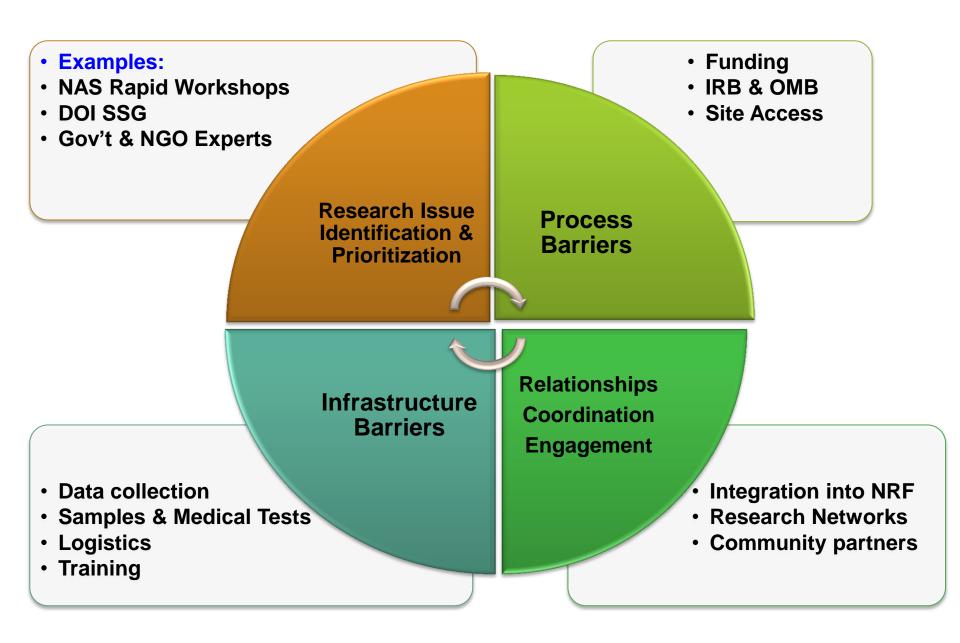
National Institutes of Health U.S. Department of Health and Human Services

NIH Disaster Research Response (DR2) Program

Improving Disaster Responses, Reducing Health Impacts, and Preventing future harm through:

- 1. Identification of important research questions and priorities
- 2. Improved access to data collection tools for researchers
- 3. Improved NIEHS & partner capability to quickly collect data
- 4. Trained researchers versed in disaster tools and issues
- 5. Integration into planning and emergency response systems
- 6. Research process including public health, academia, and impacted workers and communities

Efforts to Improve Timely Research in Four Areas



Identifying Research Priorities

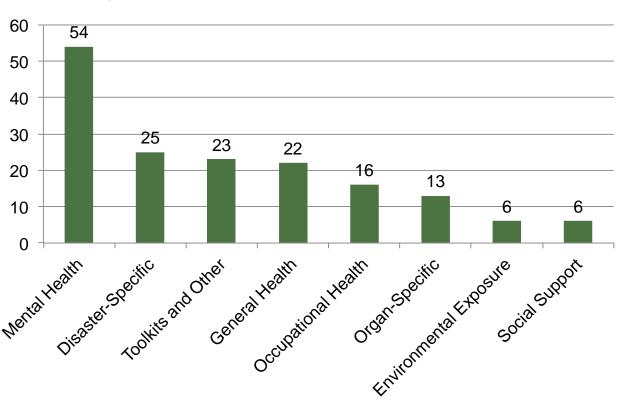
- Improved use of Networks
 - NIH Environmental Health Sciences Network
 - NIH Disaster Interest Group & ASPR SPIRIT
- Exploring other models
 - DOI Science Support Group (SSG)
 - National Academies of Science (Hurricane Sandy, Gulf Spill)
 - New: NAS Committee to pull together experts for disasters
 - -Ebola Research Priorities Workshop (Nov. 2014)*
 - -Zika Virus Workshop (Feb. 2016)



DR2 Repository of Data Collection Tools Surveys, Questionnaires, Protocols, Guidance, Forms

- 165 Tools to help start early baselines and identified research
- Implementation guidance, forms, training (e.g., consents, clinical testing)
- Available to all researchers regardless of event

8 categories initially



NIH DR2 Tools - Compiling Metadata for Repository

- Short Description and # of Items
- Purpose and Uses
- Mode of Administration
- Time to Administer
- Population of Interest
- Existence of Validity Studies

- Languages/Reading Level
- Special Interviewer Training
- History of Use in the Disaster Setting
- Professional Admin Requirements
- Ease of Use in Disaster
- Availability

New Improvements under way:

- Tools: downloadable files (MS Word & EpiInfo) for paper or electronic entry
- Improved searching and sorting into categories
- Creation of Survey Builder functionality using EpiInfo

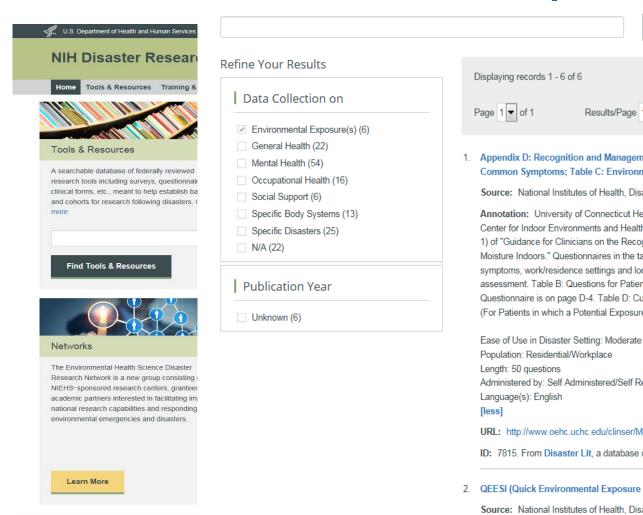
NIH DR2 Web Site

Tools & Resources

http://dr2.nlm.nih.gov

Clear Search Terms

Print/Download



Displaying records 1 - 6 of	6	Expand All	Collapse All
Page 1 ▼ of 1	Results/Page 10 ▼	Sort Newest First ▼	

1. Appendix D: Recognition and Management of Mold-Related Illness Table B: Questions for Patients with Common Symptoms; Table C: Environmental Questionnaire; Table D: Current Symptoms

Source: National Institutes of Health, Disaster Research Response Project

Annotation: University of Connecticut Health Center, Division of Occupational and Environmental Medicine, Center for Indoor Environments and Health has mold questionnaires in Tables B, C, and D of Appendix D (page D-1) of "Guidance for Clinicians on the Recognition and Management of Health Effects related to Mold Exposure and Moisture Indoors." Questionnaires in the tables consist of a general health history, items pertaining to possible symptoms, work/residence settings and locations for the respondent, potential exposures, and diagnostic assessment. Table B: Questions for Patients with Common Symptoms is on page D-3. Table C: Environmental Questionnaire is on page D-4. Table D: Current Symptoms: History and Relationship to Home, Work, or School (For Patients in which a Potential Exposure to Mold Exists) is on page D-6.

Administered by: Self Administered/Self Report

URL: http://www.oehc.uchc.edu/clinser/MOLD%20GUIDE.pdf

ID: 7815. From Disaster Lit, a database of the U.S. National Library of Medicine.

2. QEESI (Quick Environmental Exposure and Sensitivity Inventory)

Source: National Institutes of Health, Disaster Research Response Project

Annotation: This validated questionnaire, the Quick Environmental Exposure and Sensitivity Inventory, or QEESI©, also known as the "TILT Test," helps researchers, doctors, and their patieents identify individuals with multiple chemical intolerances. The QEESI was developed as a screening questionnaire for multiple chemical intolerances (MCI). The instrument has four scales: Symptom Severity, Chemical Intolerances, Other Intolerances, and Life Impact. It can be used to assess the onset of new or intensified symptoms following an event.

NIEHS Rapid Response Data Collection Team Support for National Research Capacity

- Deployment of Intramural Clinical Program Assets (support contract)
 - Technical Support (assistance with questionnaires etc.)
 - Field support for data and specimen collection for others
 - NIEHS Study Implementation
 - Rapid Acquisition of Pre/Post Incident Data (RAPIDD)
 - Questionnaires
 - Biospecimen Collection
 - Medical Testing



Rapid Acquisition of Pre/Post Incident Disaster Data (RAPIDD) Protocol

- Reduce the time it takes to initiate data collection
 - Pre-reviewed by IRB (NIEHS IRB provisional approval granted May 2015)
 - Standardized methods using established instruments
 - Pre-positioned study documents, questionnaires, supplies, and staff
- Initial Goal: Timely research of workers involved in a response
 - Contact information for cohort development
 - Gather early survey information
 - Collect biospecimens and baseline medical tests (e.g., PFT)
 - Core: 29 questions ~ 5 mins
 - Basic: 89 questions ~ 10 mins
 - Enhanced: 184 questions ~20 mins

Questionnaire

Questionnaire & Brief Description	# Questions	Estimated Time	Select?
Registry Basic Core Form	26	5 minutes	Yes□ No□
Registry Enhanced Core Form	36	10 Minutes	Yes□ No□
Demographics and Sociological Factors	16	5 Minutes	Yes□ No□
ERHMS/ATSDR Based Deployment Module	8	Unavailable	Yes□ No□
General Health			Yes□ No□
ACE General Survey – Medical History Module F.	19	Unavailable	Yes□ No□
ERHMS Basic Pre – Deployment Health Screening	12	Unavailable	Yes□ No□
ACE General Survey - Acute Health Effects Module B	57	Unavailable	Yes□ No□
Rand Medical Outcomes Study Short Form Survey 20	20	5- 10 minutes	Yes□ No□
Veterans Rand 12 Health Survey (VR-12)	12	7 Minutes	Yes□ No□
NHANES 2013 -2014 Physical activity/ Fitness Module	21	Unavailable	Yes□ No□
Measures of Overall Psychological Well-Being			Yes□ No□
Kessler 6 (K6)	6	2-3 minutes	Yes□ No□
Kessler 10 (K10)	10	5 Minutes	Yes□ No□
Measure(s) of Post-Traumatic Stress Disorder (PTSD),			Yes□ No□
PTSD Self Rating Scale (PTSD-SRS)	17	Unavailable	Yes□ No□
Primary Care PTSD Screen (PC-PTSD)	4	1-2 Minutes	Yes□ No□
Impact of Event Scale Revised (IES-R)	22	10 Minutes	Yes□ No□
Measure(s) of Anxiety and Depression			Yes□ No□
Zung Self Rated Depression Scale	20	10 Minutes	Yes□ No□
Patient Health Questionnaire (PHQ)	11	5 Minutes	Yes□ No□

IRB Approval Before Initiating Study

ype of Disaster	I Amendment Checklist Man-made and Technological Disasters
atural Disasters	Man-made and Technolog
Earthquake/Tsunami	□Chemical release/Oil spill
	☐Biological emergency
Flood	□Radiological/Nuclear
Hurricane	□Explosion
□Tomado	□Civil unrest/ war
□Wildfire	ht Utility service disruption/blackout
☐Extreme Temperature/Drough	
Other:	er and justification for deployment:
Research Setting:	
4 Sample Size:	
Estimated Sample Size:	
Estimated Sample Size:	
Estimated Sample Size:	□Spirometry □Nail clipping collection
Estimated Sample Size:	□Spirometry □Nail clipping collection □Saliva collection
Estimated Sample Size:	□Spirometry □Nail clipping collection □Saliva collection □Buccal cell collection
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Estimated Sample Size:	□Spirometry □Nail clipping collection □Saliva collection □Buccal cell collection □Hair collection orocedure and list document changes and section numbe
Estimated Sample Size: Accrual duration: Procedures: Vital signs Pulse Oximetry Anthropometry Venipuncture Fingerstick Urine collection Other: (Provide description of p in section X of this sheet	□Spirometry □Nail clipping collection □Saliva collection □Buccal cell collection □Hair collection orocedure and list document changes and section number.) all that will be completed during the visit):
Estimated Sample Size:	□Spirometry □Nail clipping collection □Saliva collection □Buccal cell collection □Hair collection

- Specifics of the disaster submitted to IRB for approval before starting study
 - Research setting
 - Sample size
 - Accrual duration
 - Procedures
 - Questionnaires
 - Outcomes of interest

- Grantees developing similar protocols
- NIEHS IRB "best practices workshop" & leading NIH
- Discussions started with OMB to support process

IRBs & Ethical Conduct of Disaster-related Research

- NIH Public Health Emergency Research Review Board (PHERRB) http://ohsr.od.nih.gov/OHSR/pherrb.php
 - Provide IRB review of protocols that are conducted or supported by HHS and are multisite studies (e.g., H1N1)
 - Standard Operating Procedures approved August 2015
- NIEHS Office of Human Research Compliance
 - Provisional approval of NIEHS RAPIDD Protocol
 - "Best Practices Working Group" to develop recommendations for IRB review of protocols in response to disasters.
 - Focusing on ethical issues including vulnerability & informed consent
 - Workshop July 2016 at NIEHS

Developing Training Materials, Field Guides, Go Kits

Field Surveys



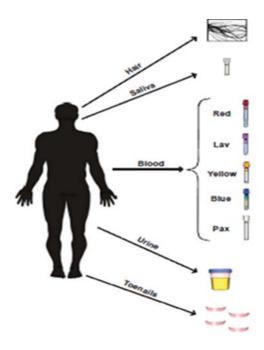
Medical Testing





Sample Collection Go Kits





Possible Biospecimens

DR2 Outreach, Implementation, & Integration with Partners Environmental Health Science (EHS) Network

Vision: working with our partners to...

Create a national "network" for timely environmental health research

Who:

- •New EHS Network Workgroup
 - NIEHS Training Program, Academic Centers, & Grantees
- Federal Partners (HHS Agencies and Others)
- Other Stakeholders
 - Public Health, Responders, & Community (incl. "citizen science")



Research Responder Training & Education

- Training & Education "those involved in research/data collection"
 - 1. National response plans and HHS mechanisms
 - Training to use DR2 and other data collections tools, protocols, etc.
 - 3. Site/Situation Specific Health and Safety Issues
- Training Exercises on identified scenarios and issues

Training Exercises

- 2014 Los Angeles & 2015 Houston
- Participants: federal, state, local, academia and community, industry
- Evaluate State and partner research capabilities & DR2 concepts & training tools
- Discussion: integration & issues of concern





Texas OneGulf Disaster Research Response



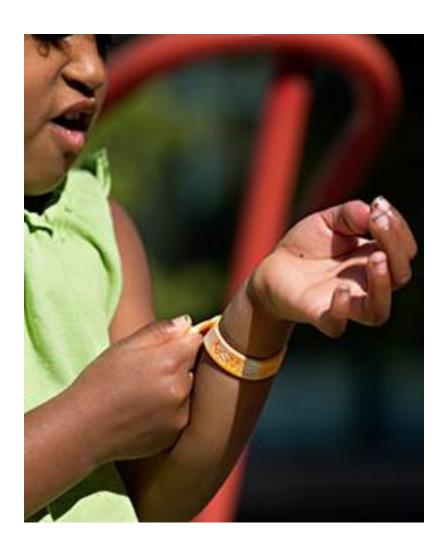


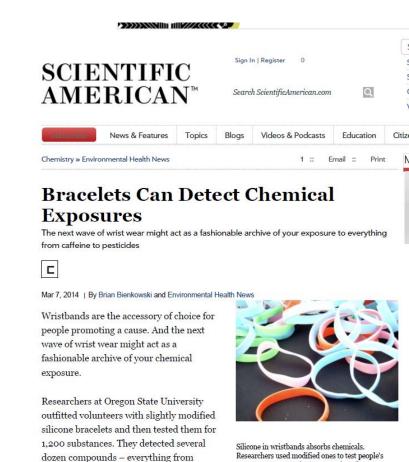






Measuring Environmental Exposures..next steps





Slide Courtesy: Dr. Kim Anderson Oregon State Univ. http://eprep.oregonstate.edu/

caffeine and cigarette smoke to flame

retardants and pesticides.

exposure to 1,200 substances, such as flame

retardants and cigarette smoke. Credit: LexnGer/Flickr

Discussion Items – Organizational Capacity

- What is your capacity to conduct timely health research after disasters?
 - Who & how are decisions made regarding involvement, support, etc.?
 - Who is available and ready to participate? Training? How fast?
 - How fast can protocols, consent forms, etc. be developed & approved?
 - Ability to implement research (e.g., operating procedures, surveys, baseline health evaluations, collect & store biospecimens)?
 - Plans for data management and communication of results?
 - Role of your IRB?

Discussion Items – Research Needs, Relationships, & Coordination

- Relationship & coordination with academia, government organizations, business, and community groups to implement health research?
 - What processes are in place to identify research needs and priorities?
 - Process for requesting support from the state, federal, others?
 - How can you be integrated into disaster health research efforts to collect needed data or information?
 - How can you coordinate with others to collect needed information?
 - How would new and existing collaborations be made and continued?

Thank You!

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DR2 Project Webpage http://dr2.nlm.nih.gov



Lesson Learned From Disaster Research Responses

- Early & consistent community engagement critical for study development, participation, implementation, & communications
- Combining federal efforts with state, academic, & community partners builds local infrastructure and resilience for the future
- Must include mental health & health care considerations during all health assessments of impacted communities
- All efforts should be made to identify issues of concern, assess exposures, and understand health effects as fast as possible